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## Patient-reported outcome after total hip arthroplasty: comparison between lateral and posterior approach

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# Patient-reported outcome after total hip arthroplasty: comparison between lateral and posterior approach

## A randomized controlled trial in 80 patients with 12-month follow-up

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**Background and purpose** — Criticism of the lateral approach (LA) for hip arthroplasty is mainly based on the risk of poor patient-reported outcomes compared to the posterior approach (PA). However, there have been no controlled studies comparing patient-reported outcomes between them. In this randomized controlled trial, we tested the hypothesis that patient-reported outcomes are better in patients who have undergone total hip arthroplasty (THA) with PA than in those who have undergone THA with LA, 12 months postoperatively.

**Patients and methods** — 80 patients with hip osteoarthritis (mean age 61 years) were randomized to THA using PA or the modified direct LA. We recorded outcome measures preoperatively and 3, 6, and 12 months postoperatively using the Hip Disability and Osteoarthritis Outcome Score–Physical Function Short Form (HOOS-PS) as the primary outcome. Secondary outcomes were HOOS-Pain, HOOS-Quality-Of-Life, EQ-5D, UCLA Activity Score, and limping.

**Results** — We found no statistically significant difference in the improvements in HOOS-PS between the treatment groups at 12-month follow-up. All secondary outcomes showed similar results except for limping, where PA patients improved significantly more than LA patients.

**Interpretation** — Contrary to our hypothesis, patients treated with PA did not improve more than patients treated with LA regarding physical function, pain, physical activity, and quality of life 12 months postoperatively. However, limping was more pronounced in the LA patients.

The choice of surgical approach in total hip arthroplasty (THA) is debated as one factor that may influence the patient-reported outcome (PRO) (Jolles and Bogoch 2004, Hendrickx et al. 2014, Repantis et al. 2015) and the risk of revision, especially revision due to dislocation (Bystrom et al. 2003, Arthursson et al. 2007, Hailer et al. 2012, Lindgren et al. 2012). Worldwide, the posterior approach (PA) and the lateral approach (LA) are 2 of the most commonly used approaches. The 2 approaches differ in several ways. The abductor muscles are partly detached during the LA procedure but are not disturbed during the PA. The detachment of the abductor muscles during LA may influence the postoperative outcomes, especially physical function. Registry-based studies have revealed small differences in PROs between the 2 approaches, favoring the PA (Amlie et al. 2014, Jameson et al. 2014, Lindgren et al. 2014). However, this difference has not been investigated in a randomized controlled trial (RCT). A systematic review concluded that there is a need for patient-reported evidence to support a particular surgical approach (Jolles and Bogoch 2004).

We conducted a prospective RCT in patients operated with the PA or the LA. The primary aim of this trial was to evaluate the efficacy of the 2 surgical approaches regarding patient-reported physical function, and the secondary aims were to evaluate their efficacy regarding patient-reported pain, physical activity, limping, and quality of life. We hypothesised that patient-reported outcomes within the first year would improve more in patients who are operated with PA rather than LA.

## Patients and methods

### Design

The trial was a blinded, parallel-group, controlled trial with balanced randomization (1:1) following the CONSORT guidelines. A full description of the protocol has already been published (Rosenlund et al. 2014).

### Participants

Patients were recruited at the Department of Orthopaedic Surgery and Traumatology, Odense University Hospital and Svendborg Hospital, Funen, Denmark, between May 2012 and May 2014. The 12-month follow-up was finalized in May 2015. Inclusion and exclusion criteria are given in Table 1. All the patients had primary osteoarthritis with indication for cementless THA. They were screened for eligibility by hip surgeons and by the principal investigator (SR).

### Intervention

All the patients had surgery at Odense University Hospital. Preoperative templating was performed using the software TraumaCad. Templating was performed to assist in restoring an equal leg length and the femoral offset. The surgeons aimed at placing the cup within 5–15° of anteversion and 30–50° of inclination (Lewinnek et al. 1978).

During surgery, the patients were positioned in the lateral decubitus position. All of them received the same types of cementless components (Bi-metric stem and Exceed ABT Ringloc-x shell and metal head, size 32 mm or 36 mm). 2 teams of 3 experienced surgeons performed all the operations. One team was responsible for the PA procedure and the other for the LA procedure.

All patients received pre- and postoperative antibiotics and thromboprophylaxis during the in-hospital stay.

### Posterior approach

PA was performed through an incision over the posterior part of the greater trochanter through the fascia, followed by blunt dissection of gluteus maximus. The external rotators were detached and the hip capsule incised (Hoppenfeld et al. 2009). The hip was dislocated by internal rotation and flexion. During closure of the wound, the capsule was repaired and the external rotators were re-inserted using a heavy absorbable suture (coated VICRYL, size 2).

### Lateral approach

LA was performed through a midline incision over the greater trochanter and involved detachment of the anterior one-third of the gluteus medius insertion and gluteus minimus insertion at the tip of the greater trochanter. The hip capsule was excised on the anterior side of the joint, from the basis of the collum femoris to the acetabular rim. The hip was dislocated by external rotation, adduction and flexion. During closure of the wound, the detached parts of the gluteus medius and mini-

Table 1. Inclusion and exclusion criteria

<p><b>Inclusion criteria</b></p> <ul style="list-style-type: none"> <li>• Aged 45–70 years</li> <li>• Diagnosed with unilateral primary hip osteoarthritis (OA) or secondary OA due to mild hip dysplasia (center-edge angle &gt; 20°)</li> <li>• Scheduled for primary cementless total hip arthroplasty<sup>a</sup></li> </ul> <p><b>Exclusion criteria</b></p> <ul style="list-style-type: none"> <li>• Symptoms in several joints (hip, knee, or ankle) with expected total joint arthroplasty within 1 year</li> <li>• Prior total joint arthroplasty at any joint (hip, knee, or ankle) or major lower limb surgery, still causing symptoms</li> <li>• BMI &gt; 35</li> <li>• Any physical disability preventing the patient from walking freely without walking aids</li> <li>• Any neurological disease (e.g. cerebral thrombosis, Parkinson's disease) compromising walking ability</li> <li>• Any severe medical condition compromising physical function (e.g. chronic heart failure, chronic obstructive pulmonary disease)</li> <li>• Severe dementia (OMC &lt; 18)</li> <li>• Inability to read and understand written and oral instructions in Danish</li> </ul> <p><sup>a</sup> Cementless Bi-metric stem and Exceed ABT Ringloc-x shell. OMC: orientation-memory-concentration test.</p>
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mus were re-inserted using a heavy absorbable suture (coated VICRYL, size 2) to re-approximate the divided gluteus minimus and the anterior flap of gluteus medius. No capsular repair was performed. A detailed description of the approach can be found in the work by Mulliken et al. (1998).

### Rehabilitation

The patients were mobilized with 2 canes and allowed full weight bearing immediately postoperatively, with no movement restrictions. They received the standard rehabilitation care of the department, which has been described in detail elsewhere (Rosenlund et al. 2014).

### Data collection

All the patients completed questionnaires preoperatively and 3, 6, and 12 months postoperatively (with 12 months as the primary endpoint).

### Patient-reported outcome measures

#### Primary outcome

We used the disease-specific Hip Disability and Osteoarthritis Outcome Score—Physical Function Short Form (HOOS-PS) as the primary outcome. HOOS-PS is a 5-item questionnaire derived from the HOOS subscales of Activities of Daily Living (HOOS-ADL) and Sport and Recreation (Davis et al. 2008). The HOOS-PS score ranges from 0 (extreme symptoms) to 100 points (no symptoms). The HOOS-PS has shown good validity when compared with the HOOS-ADL, and high responsiveness in THA patients (Davis et al. 2009).

#### Secondary outcomes

We used subscales of the Hip Disability and Osteoarthritis Outcome Score (HOOS 2.0)—Pain (HOOS-Pain) and Quality

Of Life (HOOS-QOL)—which range from 0 (extreme symptoms) to 100 points (no symptoms) (Thorborg et al. 2010, Roos 2012).

The patients completed the validated, transcultural, translated Danish versions of the HOOS-PS, HOOS-Pain, and HOOS-QOL (Nilsdotter et al. 2003, Beyer et al. 2008, Thorborg et al. 2010).

#### *EQ-5D-3L*

The Danish version of the EuroQol-5-Dimension-3-Likert-scale Health Questionnaire (EQ-5D-3L) (Brooks 1996, Gudex and Sørensen 1998) was used to assess health-related quality of life. The global health status index ranges from  $-0.624$  (worst) to  $1.0$  (best) (Wittrup-Jensen et al. 2009). The overall health status (EQ-5D-VAS) is scored on a “thermometer-like” 100-point visual analog scale from 0 (worst imaginable) to 100 (best imaginable) (van Reenen and Oppe 2015).

#### *UCLA Activity Score*

A Danish version of the University of California Los Angeles (UCLA) Activity Score was used to measure the patient-reported activity level. It uses an ordinal 10-point (1–10) Likert scale ranging from “wholly inactive: dependent on others” to “regularly participate in impact sports or heavy labour”, with a higher score being better (Terwee et al. 2011).

#### *Limping*

We used the question about limping from the function domain of the Harris hip score (HHS). Limping is scored on an ordinal 4-point (1–4) Likert scale (no limping; slight, moderate, or severe limping), with a lower score being better. This means that a single-point change will make the patient change category e.g. from no limping to slight limping. The question was used to evaluate the patient’s own perception of his/her gait function (Mahomed et al. 2001).

#### *Adverse events*

We performed a medical audit 12 months postoperatively. The following complications were registered: deep infection, periprosthetic fracture, dislocation, aseptic loosening, nerve injury, pulmonary embolism, and deep vein thrombosis.

#### *Data processing*

All questionnaires were optimized for digital scanning to reduce typing errors (Paulsen et al. 2012). Manual validation was performed where ambiguous data occurred.

#### *Sample size*

The sample size calculation was based on the primary outcome HOOS-PS, using 1 preoperative assessment and 3 follow-up assessments, and an estimated correlation between follow-up measurements of  $0.5$ . We considered the minimal clinically important difference (MCID) to be 10 points between treatment groups at the 12-month follow-up (Ehrich et al. 2000,

Roos and Lohmander 2003, Terwee et al. 2009, Roos 2012) and used a standard deviation of  $16.7$  preoperatively and  $16.1$  postoperatively (Davis et al. 2009). To achieve a statistical power of  $\beta = 0.80$  and  $\alpha = 0.05$ , 29 patients were needed in each treatment group. To account for possible dropouts, 40 patients were included in each treatment group.

#### *Randomization*

Balanced 1:1 block randomization was performed using a computer-generated list, with 4 blocks of 20 patients in each. The sequence was generated by a third person who was not involved in the trial (JL). The sequence was written on paper and placed in sealed opaque consecutively numbered envelopes by a secretary not involved in the trial. The envelopes were opened in the order given, and the patient was allocated to a treatment group and scheduled for surgery.

#### *Blinding*

The patients were blinded to treatment and informed, prior to participation, that the type of intervention would not be revealed to them. The reason for blinding was explained to them. Due to the nature of the intervention, the surgeons, ward doctors, nurses and physiotherapists were not blinded. However, they were all well aware of the importance of not discussing the intervention with the patients. Since all the patients were treated with the same rehabilitation protocol, there was no need to discuss the specific intervention. The principal investigator was kept blind throughout the trial and the statistical analyses.

#### *Ethics, registration, funding and conflict of interest*

The trial was approved by the Danish Data Protection Agency and the Danish Regional Committee on Biomedical Research Ethics (Southern Denmark) (project-ID: S-20120009). It was also registered at ClinicalTrials.gov (identifier: NCT01616667).

The trial was supported by the Danish Rheumatoid Association, University of Southern Denmark, Region of Zealand, Region of Southern Denmark, the Bevida Foundation, the Bjarne Jensen Foundation, and Odense University Hospital. None of the trial sponsors played any role in the trial design, data collection, data analysis, or interpretation; nor did they have any influence on the writing of the manuscript or the decision to submit the manuscript for publication.

The trial received funding from public and private foundations. One author (SO) has received grants from biomedical companies not related to this trial. No other competing interests declared.

#### *Statistics*

Descriptive statistics are reported with mean and standard deviation (SD) or median and interquartile range (IQR).

To evaluate the treatment effect (the mean difference in improvement between the PA and LA treatment groups at 12



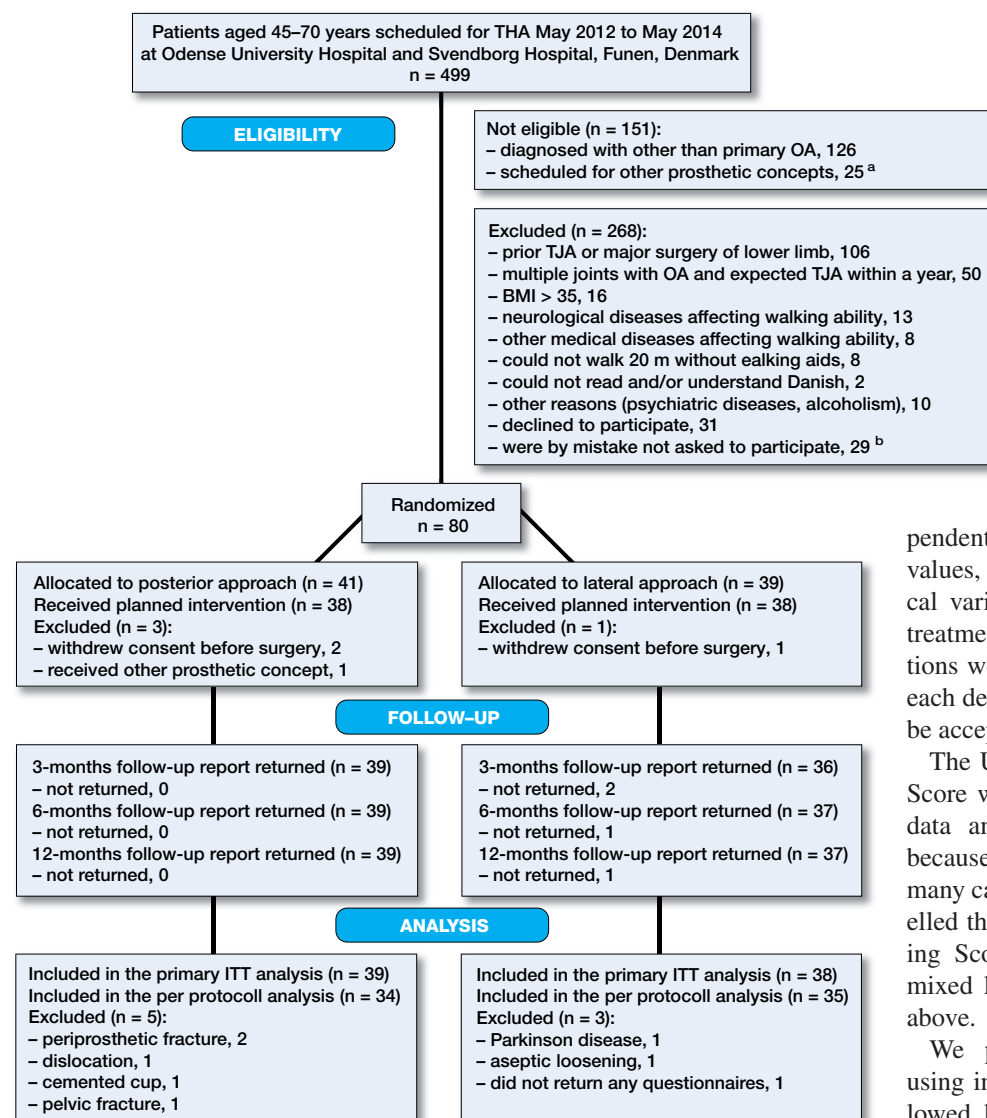


Figure 1. Flow of patients included in the trial. THA: total hip arthroplasty; OA: osteoarthritis; ITT: intention-to-treat analysis. <sup>a</sup> All concepts that were not cementless Bi-metric stem and Exceed ABT Ringloc-x shell. <sup>b</sup> Dropout analysis was performed for these patients.

months), we used mixed linear model analysis (with repeated measures) and point estimates (Rabe-Hesketh and Skrondal 2008). This model included the interaction between treatment and elapsed time, adjusted for preoperative values and assuming that data were missing completely at random (MCAR) (Rabe-Hesketh and Skrondal 2008). Where data were missing preoperatively, the mean or median preoperative value from all the other patients was imputed (used on 3 patients: 2 UCLA Activity Scores and 1 EQ-5D-VAS). Given the small amount of data imputation, it did not change the results. Otherwise, no data imputation was performed. We used the absolute score on the outcome variable as the dependent variable with patient as the random effect factor, and based the model on the restricted maximum likelihood estimate. The inde-

pendent variables were the preoperative values, treatment group, time as a categorical variable, and the interaction between treatment group and time. Model assumptions were checked with residual plots for each dependent variable and were found to be acceptable.

The UCLA Activity Score and Limping Score were a priori considered as ordinal data and treated accordingly. However, because of the limited sample size and the many categories in each outcome, we modelled the UCLA Activity Score and Limping Score as numerical scales and used mixed linear model analysis as described above.

We performed the primary analyses using intention-to-treat (ITT) analysis followed by a per-protocol analysis. Effect size (using Cohen's *d*) was calculated for continuous dependent variables. Effect sizes of 0.2, 0.5, and 0.8 were defined as being small, medium, and large, respectively (Cohen 1992).

The statistical analyses were performed using Stata 13.1 software, with a significance level of 0.05.

## Results

499 patients aged 45–70 years received primary THA in the study period (Figure 1). Of these, 151 were not eligible. Of the remaining 348 patients, 208 were excluded. 140 patients were eligible but 31 declined to participate and, by mistake, 29 were not asked to participate. 80 patients were randomized and 77 and 69 patients were available for the ITT analysis and per-protocol analysis, respectively.

The dropout analysis showed that statistically significantly more females and patients with ASA class 2 were present in

Table 2. Demographic and clinical characteristics of patients in each treatment group

	Lateral approach (n = 38)	Posterior approach (n = 39)
<b>Demographic patient characteristic</b>		
Male, n	26	26
Age at surgery, mean (SD)	60 (7)	62 (6)
BMI, mean (SD)	27 (3)	28 (4)
Affected side, right	20	19
ASA class 1; 2; 3, n	28; 7; 3	30; 6; 3
OMC score, mean (SD)	27 (2)	26 (2)
<b>Clinical characteristics</b>		
Preoperative Hgb, mmol/L, mean (SD)	9.1 (0.8)	8.9 (0.6)
Postoperative Hgb, (mmol/L), mean (SD)	6.9 (1.2)	6.9 (0.9)
Blood loss, mL, mean (SD)	363 (171)	362 (140)
Received blood transfusion, n	2	1
Anesthesia, n		
Spinal	32	26
General	6	13
Duration of surgery, min, mean (SD) <sup>a</sup>	60 (12)	54 (13)
Prosthetic head size, n		
32 mm	30	33
36 mm	8	6
Stem type, n <sup>b</sup>		
Standard	30	19
Lateralized	8	20
<b>Preoperative patient-reported outcomes</b>		
HOOS-PS, mean (SD)	53 (14)	53 (17)
HOOS-Pain, mean (SD)	44 (15)	43 (17)
HOOS-Quality Of Life, mean (SD)	29 (12)	28 (14)
EQ-5D-3L, mean (SD)	0.6 (0.2)	0.6 (0.2)
EQ-5D-VAS, mean (SD)	60 (18)	57 (25)
UCLA Activity Score, median (IQR)	5 (4–7)	5 (3–6)
Limping Score, median (IQR)	3 (3–3)	3 (3–3)

BMI: body mass index;

ASA: American Society of Anaesthesiology classification;

OMC: orientation-memory-concentration test (0 = worst outcome, 28 = best outcome);

Hgb: hemoglobin;

HOOS: Hip Disability and Osteoarthritis Outcome Score (scores range from 0 to 100, with higher scores indicating better outcome);

EQ-5D-3L: European Quality of Life Health Questionnaire (scores range from -0.624 to 1.0, with higher scores indicating better outcome);

EQ-5D-VAS: European Quality of Life visual analog scale of overall

state of health (scores range from 0 to 100 with higher scores

indicating better outcome);

UCLA Activity Score: the University of California Los Angeles Activity Score (scores range from 1 to 10 with higher scores indicating better outcome).

Limping score: ranges from 1 (no limping) to 4 (severe limping).

<sup>a</sup> Significant difference between treatment groups tested with Student's t-test.

<sup>b</sup> Significant difference with the chi-square test.

the group of patients who were not included (Appendix A, see Supplementary data).

8 patients (3 in the LA group and 5 in the PA group) did not follow the protocol for various reasons (Figure 1).

Preoperative patient characteristics and surgically related outcomes are presented in Table 2. There was no difference between the groups regarding femoral head size, but more patients in the LA group received a lateralized stem.

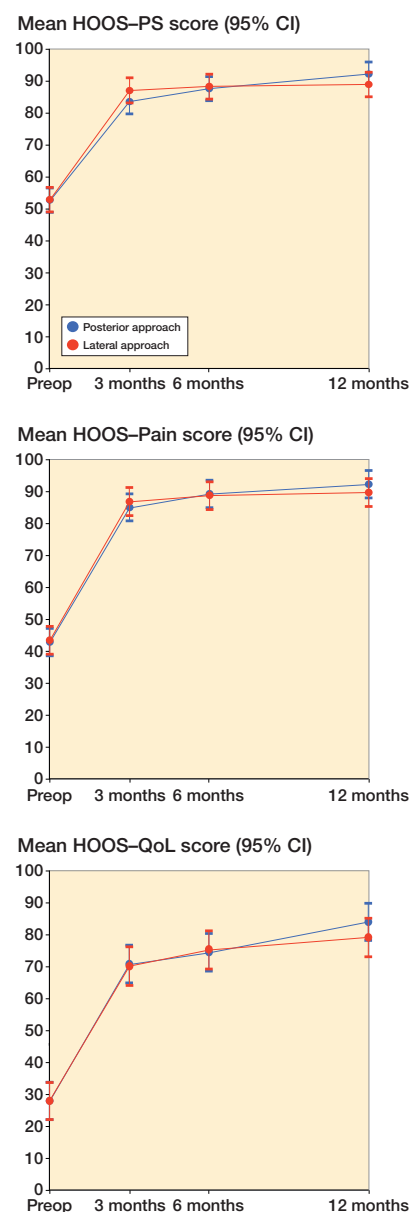


Figure 2. HOOS-PS (top panel), HOOS-Pain (middle panel) and HOOS-QoL (quality of life; bottom panel), by time and treatment group. Mean scores with 95% CI.

### Patient-reported outcomes

Within- and between-group change scores are given in Table 3. We found a statistically non-significant difference in the mean change score in HOOS-PS of -3.3 (95% CI: -8.7 to 2.1). Thus, the improvement in physical function 12 months post-operatively following PA treatment was not any better than the improvement following LA treatment. The same applies to all the earlier time points (Figure 2A). Furthermore, there was no additional improvement in the PA group (compared to the LA group) in the secondary outcomes at any time-point (HOOS-Pain, HOOS-QOL, UCLA Activity Score, EQ-5D-3L, and

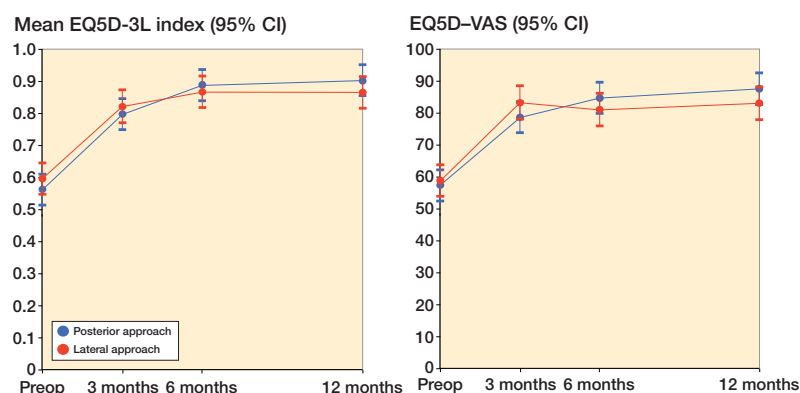


Figure 3. EQ-5D-3L (left panel) and EQ-5D-VAS (right panel) by time and treatment group. Mean scores with 95% CI.

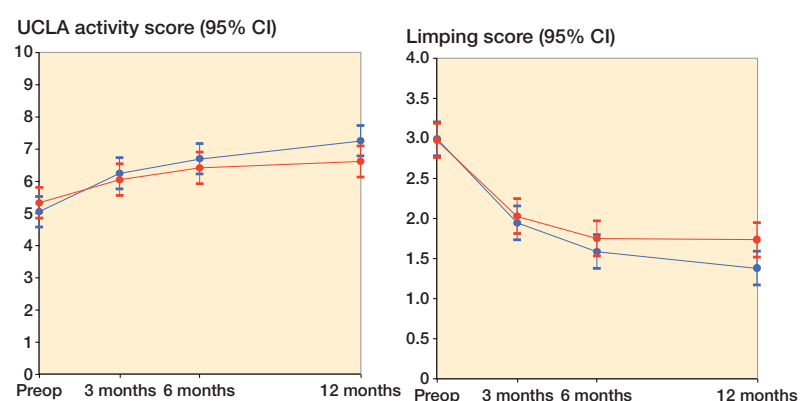


Figure 4. UCLA Activity Score and Limping Score, by time and treatment group. Mean scores with 95% CI.

EQ-5D-VAS) (Figures 2 and 4, and Table 3). A significant between-group difference in favor of PA was observed for

limping (0.4, 95% CI: 0.0–0.7) (Figure 4 and Table 3). Collectively, all outcome measures tended to have a higher numeric improvement for PA. The effect size (Cohen's d) for the primary outcome at 12 months was small (0.3, 95% CI: –0.2 to 0.7) (Table 3).

The per-protocol analysis changed the results on limping to a statistically non-significant improvement in favor of PA. All other results remained unchanged (Appendix B, see Supplementary data). A significant within-group improvement in HOOS-PS was observed in both treatment groups: 39 (95% CI: 35–44) and 36 (95% CI: 30–42) for PA and LA, respectively. The greatest improvement in all outcomes occurred within the first 3 months (Figures 2–4).

A number-needed-to-treat analysis is available in Appendix C (see Supplementary data).

### Adverse effects

5 patients in the PA group had adverse events. 2 had a periprosthetic fracture within 1 month of surgery (1 accidentally fell; the other had a peroperative fissure in the proximal femur, probably leading to the periprosthetic fracture). Both patients had a revision and became well-functioning. 1 had a dislocation 3 weeks postoperatively, was treated with closed reduction, and became well-functioning. 2 patients had a deep vein thrombosis and were treated medically. 1 patient in the LA group had a revision due to aseptic loosening of the stem. He

became relatively well-functioning despite sequelae with a drop foot.

Table 3. Mean difference in patient-reported outcomes within and between treatment groups preoperatively to 12-month follow-up (intention to treat). Values are mean (95% CI) unless otherwise indicated

PROM	Within-group change Preoperatively to 12-month follow-up		Between-group change (LA minus PA) <sup>a</sup> Preoperatively to 12-month follow-up		Cohen's d, effect size (ES) 12-month follow-up ES (95% CI)
	Lateral approach (n = 37)	Posterior approach (n = 39)	(n = 77)	p-value	
HOOS-PS	36 (30 to 42)	39 (35 to 44)	–3.3 (–9 to 2)	0.2	0.3 (–0.2 to 0.7)
HOOS-Pain	46 (40 to 53)	50 (44 to 55)	–2.6 (–9 to 4)	0.4	0.1 (–0.3 to 0.6)
HOOS-QOL	51 (42 to 59)	56 (50 to 61)	–4.9 (–13 to 4)	0.3	0.2 (–0.2 to 0.7)
EQ-5D-3L	0.3 (0.2 to 0.3)	0.3 (0.3 to 0.4)	–0.04 (–0.11 to 0.03)	0.3	0.1 (–0.4 to 0.5)
EQ-5D-VAS	24 (16 to 32)	30 (23 to 38)	–5 (–12 to 3)	0.2	0.2 (–0.2 to 0.7)
UCLA Activity	1 (0 to 3) <sup>c</sup>	2 (1 to 3) <sup>c</sup>	–0.6 (–1.3 to 0.0)	0.06	– <sup>b</sup>
Limping Score	–1 (–2 to –1) <sup>c</sup>	–2 (–2 to –1) <sup>c</sup>	0.4 (0.0 to 0.7)	0.02	– <sup>b</sup>

For PROM abbreviations, see Table 2

<sup>a</sup> Results from a random-effects mixed linear model analysis (repeated measures) with PROM variable as the dependent variable and preoperative value, treatment, time, and interaction between time and treatment as independent variables. Data from all assessment time points (preoperatively and 3, 6, and 12 months postoperatively) were used in the model. A numerically positive value indicates a better outcome for LA, except for limping.

<sup>b</sup> Cohen's effect size was not calculated due to the ordinal nature of the outcome.

<sup>c</sup> median (IQR)



## Discussion

The main aim of this trial was to investigate whether the efficacy—evaluated by improvement in patient-reported outcome—was better in patients who underwent THA with PA rather than THA with LA, 12 months postoperatively.

Contrary to our hypotheses, no statistically significant difference in improvement in physical function was observed between the patients in the 2 groups. The same applied to the secondary outcomes except for limping, where patients in the PA group improved more than the patients in the LA group.

There was, however, a systematic tendency towards higher numeric improvements in the PA group, ranging from 2.6 to 4.9 points on HOOS-Pain, HOOS-PS and HOOS-QOL, than in the LA group. These findings are in agreement with a cohort study of 852 THA patients operated with LA or PA, with 1–3 years of follow-up. That study showed a statistically significant difference of 4.0 points on the HOOS-ADL subscale in favor of the PA group (Amlie et al. 2014). Also, a randomized study with 3-month follow-up showed this tendency in both surgeon-reported and patient-reported outcomes (Witzleb et al. 2009), although the differences were not statistically significant.

We found a between-group difference in general health status (EQ-5D-3L) of  $-0.04$  (95% CI:  $-0.1$  to  $0.03$ ). This corresponds to findings from a registry-based study of 42,233 THA patients with 6 years of follow-up. That study showed a statistically significantly better EQ-5D outcome (by 0.03) in favor of the PA group (Lindgren et al. 2014). However, the differences in both HOOS and EQ-5D between the 2 approaches were small, and it can be questioned whether the differences are above the minimal clinically important difference (MCID) (Ehrich et al. 2000, Roos and Lohmander 2003, Terwee et al. 2009, Larsen et al. 2010, Roos 2012, Coretti et al. 2014). The effect size (Cohens'  $d$ ) also supports this notion, as the effect size for all outcomes was small to negligible.

We based the sample size calculation on the HOOS-PS subscale with 10 points as the MCID between groups. This decision was based on published evidence and related RCT studies using the HOOS questionnaire as the primary outcome measure (Ehrich et al. 2000, Roos and Lohmander 2003, Terwee et al. 2009, Roos 2012, Skou et al. 2012, Villadsen et al. 2014). We cannot rule out the possibility of type-II error in our study, if the MCID is less than 10 points as we used. A post-hoc sample size calculation showed that to detect a statistically significant between-group difference in HOOS-Physical Function of 3.3 points, using the standard deviations from our trial, 183 patients would be required in each treatment group. However, we consider that the statistically non-significant between-group difference of  $\sim 3$  HOOS points in all the HOOS subscales included, in favor of PA, was not clinically relevant—based upon current evidence (Frobell et al. 2008, Roos 2012, Villadsen et al. 2014, Kise et al. 2015, Kise et al. 2016). This does not imply that there could be no

other clinically significant differences than those investigated in our study.

We found that patients in the PA group reported having less limping than patients in the LA group, which may be explained by the disturbance of the abductor muscles (Masonis and Bourne 2002, Edmunds and Boscainos 2011, Amlie et al. 2014). The difference was, however, less than 1 point. A single-point change is what differentiates 2 categories, e.g. the difference between no limping and slight limping on the 4-point Likert scale. The difference was not statistically significant in the per-protocol analysis. Our results are in line with those from a cohort study that found twice as many patients in the LA group with self-reported limping at 1–3 years postoperatively (Amlie et al. 2014). That study also found that the difference in mean score between patients with and without self-reported limping ranged from 17 to 35 on the 5 HOOS subscales, in favor of the non-limping patients. In contrast to our results, a Cochrane review based on 4 non-randomized cohort studies found no differences in limping between patients operated with LA or with PA, as measured with the Trendelenburg test (Jolles and Bogoch 2004). Also, the study by Winther et al. (2015) could not detect any difference in hip muscle strength at 3 months between the PA patients and the LA patients. However, the patients' perception—and hence response to the question—of limping may not match an objective measurement of limping.

## Strengths and limitations

Regarding strengths, the study was a thoroughly executed, randomized controlled trial following the CONSORT statement. We randomized the patients to a specific approach that automatically included a specific team of surgeons with skills in that particular approach, thus avoiding bias due to a learning curve. To avoid the risk of comparing surgeon skills or surgeon preference rather than the surgical procedure, 3 equally experienced surgeons participated in each team.

Regarding limitations, the study was designed as a superiority trial. We cannot therefore conclude that LA is not inferior to PA. If the clinically relevant difference was less than 10 points on the HOOS subscales, the study may have been underpowered to show this with a statistically significant value. Furthermore, this trial was designed to investigate group differences between PA and LA rather than at the individual level, which has been suggested by Katz et al. (2015). At the individual level, we found that 23 patients in the LA group had a HOOS-PS score of over 88 points—as compared to 27 in the PA group, giving a non-significant absolute risk reduction of 7% (95% CI:  $-14$  to  $28$ ). The number needed to treat (NNT) was 14 in favor of PA, but the result was not statistically significant based on the present sample size (Appendix C, see Supplementary data).

Blinding of both the patients and the principal investigator performing the analyses was maintained almost completely throughout the trial, due to the nature of the self-reported

outcomes and through the discretion of the hospital personnel. We are aware that a few patients may have guessed their intervention. However, we did not systematically measure the success of blinding.

Disadvantages related to THA surgery, such as dislocation rates and revision rates, are relevant to include in the investigation of potential differences between the 2 surgical approaches, but this would require a longer follow-up and a study design with a larger sample size (Jolles and Bogoch 2004). These issues should be addressed before making any firm conclusion about the superiority of one approach over the other.

### Generalizability

Not all eligible patients (43%) were included in the trial, which may have reduced the external validity. The strict exclusion criteria may have limited any generalizability of the results to other patient groups. However, 80% of all THA patients are diagnosed with primary osteoarthritis (Overgaard 2013), so the patients in this trial represent the vast majority of all THA patients.

### Conclusion

We found no superior efficacy of using the PA compared with LA, as evaluated from patient-reported physical function, pain, physical activity, and quality of life. However, patients operated using the PA had less self-reported limping at 12 months. A future multicenter non-inferiority RCT would be valuable to investigate whether there are significant differences in revision rates between THAs performed with the LA and with the PA.

### Supplementary data

Appendices A–C are available as supplementary data in the online version of the article <http://dx.doi.org/10.1080/17453674.2017.1291100>.

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SR, AHL, CJ, LB, and SO were responsible for the concept and design of the trial. SR was responsible for inclusion of patients and collection of data on all patients included, analysis of data, and drafting of the manuscript. All the authors were responsible for interpretation of the data and performed critical revision of the manuscript.

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